

**IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF OHIO
WESTERN DIVISION**

OHIO STANDS UP!, et al.,)	Case No.: 3:20-cv-02814-JRK
)	
Plaintiffs,)	
)	JUDGE JAMES R. KNEPP, II
v.)	
)	
THE UNITED STATES)	FEDERAL DEFENDANTS'
DEPARTMENT OF HEALTH)	MOTION TO DISMISS
AND HUMAN SERVICES, et al.,)	
)	
Defendants)	

NOW COMES the United States of America, by and through Bridget M. Brennan, Acting United States Attorney for the Northern District of Ohio, and Angelita Cruz Bridges, Assistant United States Attorney, and respectfully moves to dismiss Plaintiffs' second Amended Complaint (Am. Compl., ECF No. 27, PageID # 248-67) against all Federal Defendants including the United States Department of Health and Human Services (HHS) and its Secretary Xavier Becerra¹; the Center for Disease Control (CDC) and its Director, Rochelle Walensky; the National Center for Health Statistics (NCHS) and its Director, Brian C. Moyer, and the Office of Management and Budget (OMB) and its Director Shalanda Young, and unnamed federal defendants John and/or Jane Doe; (collectively "Federal Defendants"). The grounds for dismissal are lack of subject matter jurisdiction and failure to state a claim upon which relief may be granted under Fed. R. Civ. P. 12(b)(1) and (6).

A Memorandum in Support follows.

Respectfully submitted,

BRIDGET M. BRENNAN
ACTING UNITED STATES ATTORNEY

¹ The second Amended Complaint names Norris Cochran, Acting Secretary of HHS. The position is currently held by Xavier Becerra, who was appointed as Secretary of HHS, following his confirmation on March 18, 2021, and is automatically substituted as a party defendant under Fed. R. Civ. P. 25(d)(1).

s/ Angelita Cruz Bridges

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MEMORANDUM IN SUPORT

I. INTRODUCTION AND PROCEDURAL BACKGROUND

On March 31, 2021, Plaintiffs filed their second Amended Complaint² seeking injunctive relief under the Paperwork Reduction Act of 1995 (PRA), 44 U.S.C. §§ 3501-3521; the Information Quality Act (IQA), 44 U.S.C. § 3516; and the Administrative Procedure Act (APA), 5 U.S.C. §§ 500-706. Plaintiffs seek a declaratory judgment that HHS is violating the PRA and IQA by using “misleading” data related to Coronavirus Disease 2019 (COVID-19) infections and deaths; injunctive relief in several forms essentially preventing HHS and other Federal Defendants from continuing to use the data in its current form to report COVID-19 infections and deaths; and a writ of mandamus compelling Federal Defendants to comply with and enforce the PRA and IQA. (ECF No. 27, PageID # 262-66.)

This Court should dismiss Plaintiffs’ second Amended Complaint because Plaintiffs fail to identify a waiver of sovereign immunity and do not have standing to bring their claims under the APA, IQA, or PRA. There is no private right of action under the IQA or the PRA and Plaintiffs do not allege any facts to support a right of judicial review under the APA. Finally, Plaintiffs’ second Amended Complaint fails to state a claim under the APA and contains vague conclusory allegations that do not state a claim for relief under any federal law.

II. STATUORY AND REGULATORY BACKGROUND

A. The Administrative Procedure Act (APA)

The APA, 5 U.S.C. §§ 701-706, establishes a waiver of sovereign immunity and a cause of action for injunctive relief for parties adversely affected either by agency action or failure to

² Plaintiffs’ first Amended Complaint was filed on February 3, 2021 and included a Motion for Temporary Restraining Order (TRO) and Preliminary Injunction. (ECF No. 10, PageID # 124-96; Mot. for TRO & Prelim. Inj., ECF No. 11, PageID # 197-209.) The Court denied the Motion for TRO and ordered Plaintiffs to file a second amended complaint that complied with Fed. R. Civ. P. 8(a)(2) and 10(b) by March 31, 2021. (Order, ECF No. 26, PageID # 246-47.) The Court held the issue of the preliminary injunction in abeyance. (*Id.* PageID # 247.)

act. *See* 5 U.S.C. §§ 702, 706(1)-(2). “[A]gency” is defined as “each authority of the Government of the United States, whether or not it is within or subject to review by another agency,” with certain exceptions. 5 U.S.C. §§ 551(1), 701(b)(1).

Plaintiffs assert claims under §§ 702 and 706 of the APA. (ECF No. 27, PageID # 256.) Pursuant to section 702, “[a] person suffering legal wrong because of agency action, or adversely affected or aggrieved by agency action within the meaning of the relevant statute, is entitled to judicial review thereof.” 5 U.S.C. § 702. Section 706(2) of the APA authorizes courts to “hold unlawful and set aside agency action, findings, and conclusions found to be . . . arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law.” 5 U.S.C. § 706(2). Review under these provisions is limited to “agency action,” which is defined as “the whole or a part of an agency rule, order, license, sanction, relief, or the equivalent or denial thereof, or failure to act.” 5 U.S.C. § 551(13); *see also* 5 U.S.C. § 701(b)(2).

The APA also limits judicial review to agency action that is “final.” *See* 5 U.S.C. § 704. To be deemed final, agency action must: (1) “mark the consummation of the agency’s decisionmaking process” and (2) “the action must be one by which ‘rights or obligations have been determined,’ or from which ‘legal consequences’ will flow.” *Bennett v. Spear*, 520 U.S. 154, 177-78 (1997) (quoting *Chicago & S. Air Lines, Inc. v. Waterman S.S. Corp.*, 333 U.S. 103, 113 (1948) and *Port of Boston Marine Terminal Ass’n v. Rederiaktiebolaget Transatlantic*, 400 U.S. 62, 71 (1970)).

B. The Paperwork Reduction Act (PRA)

The PRA was enacted to reduce the burden of paperwork requests on the public. 44 U.S.C. § 3501-3521; *see Dole v. United Steelworkers of Am.*, 494 U.S. 26, 32 (1990) (*superseded by statute*, Paperwork Reduction Act of 1995) (the PRA “prohibits any federal agency from adopting regulations which impose paperwork requirements on the public unless the information is not available to the agency from another source within the Federal Government....”); *Cuzco-Mora v. Holder*, 592 F. App’x. 437, 441 (6th Cir. 2014) (“Congress enacted the PRA to reduce the federal

paperwork burden on individuals, small businesses, state and local government, and other persons ...”).)

The PRA requires federal agencies seeking to collect certain information from the public to first obtain approval from OMB. 44 U.S.C. § 3506(c). Notably, the PRA does not apply to every instance of an agency’s attempt to obtain or solicit information from the public. Instead, the Act requires OMB approval only of “collection[s] of information,” as defined at 44 U.S.C. § 3502(3). Thus, if an agency does not seek to collect “information” from the public, as defined by OMB regulations, its “collection of information” is not subject to the PRA. *Id.* Most importantly here, the PRA does not authorize a private right of action; Congress expressly precluded courts from reviewing any decision by OMB either to “approve or not act upon a collection of information contained in an agency rule.” 44 U.S.C. § 3507(d)(6).

C. The Information Quality Act (IQA)

The IQA directs the Director of OMB to issue guidelines for information quality and to require federal agencies to establish policies and procedures on the same. 44 U.S.C. §§ 3504, 3506, 3516. “By its terms, [the IQA] creates no legal rights in any third parties,” and “does not create a legal right to access to information or to correctness....” *Salt Inst. v. Leavitt*, 440 F.3d 156, 159 (4th Cir.2006); *Zero Zone, Inc., v. U.S. Dep’t of Energy*, 832 F.3d 654, 683 n. 25 (7th Cir. 2016) (citing *Miss. Comm’n on Env’tl. Quality v. EPA*, 790 F.3d 138, 184 (D.C. Cir. 2015) (quoting *Leavitt*, 440 F.3d at 159 “almost every court that has addressed an Information Quality Act challenge has held that the statute ‘creates no legal rights in any third parties.’ ”); *Harkonen v U.S. Dep’t of Justice*, 800 F.3d 1143, 1148 (9th Cir. 2015) (“Absent a statutory provision, an individual can not (sic) assert a cause of action against the government for the dissemination of inaccurate, incorrect, or defamatory information.”)

III. LEGAL STANDARDS

A. Standard for a Motion to Dismiss for Lack of Jurisdiction

Plaintiffs bear the burden of establishing subject matter jurisdiction under Fed. R. Civ. P.

12(b)(1). *Hedgepeth v. Tennessee*, 215 F.3d 608, 611 (6th Cir. 2000). The Sixth Circuit has construed the “statutory authority evidencing the consent of the sovereign to be sued” as a jurisdictional prerequisite. *Cleveland Chair Co. v. United States*, 526 F.2d 497, 498 (6th Cir. 1975). A defendant may challenge the existence of subject matter jurisdiction by attacking the complaint on its face or by relying on evidence beyond the pleadings to attack the factual basis for subject matter jurisdiction. *Glob. Tech., Inc. v. Yubei (Xinxiang) Power Steering Sys. Co.*, 807 F.3d 806, 810 (6th Cir. 2015).

When a defendant attacks a complaint as deficient on its face, “a district court takes the allegations in the complaint as true....” *Gentek Bldg. Prods. v. Sherwin-Williams Co.*, 491 F.3d 320, 330 (6th Cir. 2007). If the “allegations establish federal claims, jurisdiction exists.” *Id.* In a factual attack, on the other hand, “no presumptive truthfulness applies to the allegations.” *Id.* A factual attack challenges “the factual existence of subject matter jurisdiction ... and the court is free to weigh the evidence and satisfy itself as to the existence of its power to hear the case.” *United States v. Ritchie*, 15 F.3d 592, 598 (6th Cir. 1994). Under either approach, Plaintiffs’ second Amended Complaint fails to establish this Court’s jurisdiction.

B. Standard for a Motion to Dismiss for Failure to State a Claim

A court will grant a motion to dismiss for failure to state a claim, pursuant to Fed. R. Civ. P. 12(b)(6), if the court finds a plaintiff “‘can prove no set of facts in support of their claims that would entitle [them] to relief.’” *Leech v. DeWeese*, 689 F.3d 538, 542 (6th Cir. 2012) (quoting *Cooley v. Strickland*, 479 F.3d 412, 415 (6th Cir. 2001)). When reviewing a motion to dismiss for failure to state a claim, the court must “accept the plaintiff’s factual allegations as true, and ... view the complaint in the light most favorable to the plaintiff, but ... [is] ‘not required to accept legal conclusions or unwarranted factual inferences as true.’” *Crosby v. Univ. of Ky.*, 863 F.3d 545, 551-552 (6th Cir. 2017) (quoting *Moody v. Mich. Gaming Control Bd.*, 847 F.3d 399, 402 (6th Cir. 2017)).

In accordance with Fed. R. Civ. P. 8(a)(2), a complaint must contain “a short and plain

statement of the claim showing that the pleader is entitled to relief.” The pleading standard under Rule 8 “does not require ‘detailed factual allegations,’ but it demands more than an unadorned, the-defendant-unlawfully-harmed-me accusation.” *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007)). Also, Fed. R. Civ. P. 10 requires each pleading contain a caption, naming all the parties, and numbered paragraphs, that state claims or defenses, each limited to a single set of circumstances. Fed. R. Civ. P. 10(a), (b).

IV. ARGUMENT

A. The Court Lacks Jurisdiction Over Plaintiffs’ Claims

1. Plaintiffs’ claims are barred by sovereign immunity.

“The United States, as sovereign, is immune from suit save as it consents to be sued.” *United States v. Sherwood*, 312 U.S. 584, 586 (1941) (citations omitted); *see also United States v. King*, 395 U.S. 1, 4 (1969). Thus, to invoke the jurisdiction of a federal court for relief against a federal agency, a litigant must identify a statute that confers subject matter jurisdiction and a federal law that waives the sovereign immunity of the United States to the cause of action. *Cleveland Chair. Co.*, 526 F.2d at 498. Any such waiver of sovereign immunity “must be unequivocally expressed in the statutory text” and “strictly construed, in terms of its scope,” in favor of the United States. *Lane v. Pena*, 518 U.S. 187, 192 (1996).

Here, Plaintiffs only identify §§ 702 and 706 of the APA as the applicable waiver of sovereign immunity. (ECF No. 27, PageID # 256.) However, the APA’s waiver does not apply where any other statute that grants consent to suit expressly or impliedly excludes a right to judicial review. *Match-E-Be-Nash-She-Wish Band of Pottawatomi Indians v. Patchak*, 567 U.S. 209, 215 (2012). That is the case here; as discussed more below, there is no right to judicial review under the PRA and IQA. 44 U.S.C. § 3507(d)(6); *Leavitt*, 440 F.3d at 159; *Zero Zone, Inc.*, 832 F.3d 654, 683 n. 25 (7th Cir. 2016).

Plaintiffs’ second Amended Complaint names various federal officials in their official and individual capacities. (ECF No. 27, PageID #253-54.) Plaintiffs briefly mention First Amendment

rights, discrimination under the Americans with Disabilities Act, a Constitutional right to freedom of movement, freedom of religion, and freedom of speech; however, they describe the “Nature of the Action,” as one brought under the APA, PRA, and IQA, not violations of the constitution. (*Id.* PageID # 251.) To the extent Plaintiffs are alleging constitutional violations committed by the individual federal officers, their claims are not permitted under the “implied cause of action theory” adopted by the Supreme Court in *Bivens*. *Ziglar v. Abbasi*, 137 S. Ct. 1843, 1851-52 (2017) (citing *Bivens v. Six Unknown Named Agents of Fed. Bureau of Narcotics*, 403 U.S. 388 (1971)).

The Supreme Court has only recognized three implied causes of action: 1) violations by “federal officers who violated the prohibition against unreasonable search and seizures”; 2) a Fifth Amendment Due Process Clause violation for gender discrimination; and 3) an Eighth Amendment violation for cruel and unusual punishments for inadequate medical treatment given to an inmate. *Ziglar*, 137 S. Ct. at 1854-1855. However, the Supreme Court has not recognized a cause of action against a federal officer in their individual capacity for constitutional violations involving “freedom of movement,” “freedom of speech” and “freedom of religion.” (ECF No. 27, PageID # 252.) The Supreme Court “has made clear that expanding the *Bivens* remedy is now a ‘disfavored’ judicial activity.” *Ziglar*, 137 S. Ct. at 1857 (quoting *Iqbal*, 556 U.S. at 675). Further, consistent with past holdings, “a *Bivens* remedy will not be available if there are ‘special factors counselling hesitation in the absence of affirmative action by Congress.’” *Id.* at 1857 (quoting *Carlson v. Green*, 446 U.S. 14, 18 (1980)). One relevant factor is determining whether “there is an alternative remedial structure present in a certain case....” *Id.* at 1858. “For if Congress has created ‘any alternative, existing process for protecting the [injured party’s] interest’ that itself may ‘amoun[t] to a convincing reason for the Judicial Branch to refrain from providing a new and freestanding remedy in damages.’” *Id.* (quoting *Wilkie v. Robbins*, 551 U.S. 537, 550 (2007)).

Here, there was an alternative remedial structure for Plaintiffs to pursue. Plaintiffs could have pursued HHS administrative remedies available for the timely “correction of information

maintained and disseminated ...” by the CDC. *Leavitt*, 440 F.3d at 158-59; *See HHS Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated to the Public* (Oct. 1, 2002), <https://aspe.hhs.gov/report/hhs-guidelines-ensuring-and-maximizing-quality-objectivity-utility-and-integrity-information-disseminated-public>.

However, Plaintiffs do not allege they pursued that process. (ECF No. 27.) The Court should not now expand the “*Bivens* remedy which is a “disfavored” judicial activity” and recognize constitutional claims against the individual federal officers. *Ziglar*, 137 S. Ct. at 1857 (quoting *Iqbal*, 556 U.S. at 675).

Based on the foregoing, Plaintiffs’ claims are barred by the doctrine of sovereign immunity and this Court lacks jurisdiction. Therefore, the second Amended Complaint should be dismissed.

2. Plaintiffs do not demonstrate standing.

“The question of standing ‘involves both constitutional limitations on federal-court jurisdiction and prudential limitations on its exercise.’” *Bennet*, 520 U.S. at 162, (quoting *Warth v. Seldin*, 422 U.S. 490, 498 (1975)). “[T]he core component of standing is an essential and unchanging part of the case-or-controversy requirement of Article III.” *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560 (1992). Plaintiffs bear the burden of establishing standing. *Id.* at 561. Where ... Congress has authorized public officials to perform certain functions according to law, and has provided by statute for judicial review of those actions under certain circumstances, the inquiry as to standing must begin with a determination of whether the statute in question authorizes review at the behest of the plaintiff.” *Sierra Club v. Morton*, 405 U.S. 727, 732 (1972).

a. No Standing Under the PRA nor IQA due to No Private Right of Action

In *Califano v. Sanders*, the Supreme Court held that the APA itself does not provide subject matter jurisdiction. *Califano v. Sanders*, 430 U.S. 99, 107 (1997). Under the APA, plaintiffs must rely on a separate statutory provision to establish a right to judicial review. Here, Plaintiffs have no statute to rely on; both the IQA and the PRA specifically exclude judicial review. *Heckler v. Chaney*, 470 U.S. 821, 830 (1985); *Leavitt*, 440 F.3d at 158; 44 U.S.C. § 3507(d)(6).

First, Section 6 of the Executive Order instituting the PRA states that “[t]his Executive order is intended only to improve the internal management of the executive branch and does not create any right or benefit, substantive or procedural, enforceable at law or equity by a party against the United States, its agencies, or instrumentalities, its officers or employees, or any other person.” Exec. Order No. 13073, 63 Fed. Reg. 6467 (Feb. 4, 1998), *as amended in* 44 U.S.C. § 3506. Section 3507(d)(6) continues that “[t]he decision by the Director [of the OMB] to approve or not act upon a collection of information contained in an agency rule shall not be subject to judicial review.” Plaintiffs allege that an NCHS alert dated March 24, 2020, (hereafter “The Alert”) issued regarding a new International Classification of Diseases (“ICD”) code is a “reporting rule” subject to judicial review, which Federal Defendants do not concede.³ (ECF No. 27, PageID # 257.) *See* Steven Schwartz, PhD, Director – Division of Vital Statistics, NCHS, *National Vital Statistics System, COVID-19 Alert No. 2* (March 24, 2020), <https://www.cdc.gov/nchs/data/nvss/coronavirus/Alert-2-New-ICD-code-introduced-for-COVID-19-deaths.pdf>. However, even if The Alert were an agency rule, Plaintiffs would not have standing because PRA § 3507(d)(6) is an explicit unequivocal statement of Congressional intent to preclude judicial review.

Further, the PRA only governs reporting requirements imposed on the public. (44 U.S.C. § 3502: “persons [who] generate, maintain, or provide information to or for a Federal agency...”.) Plaintiffs do not allege they are required to report information to Federal Defendants. (ECF No. 27, PageID # 251-53.) Persons required to report information under the PRA may only bring claims under the PRA’s “public protection” provision, found at 44 U.S.C. § 3512, which states: “no person shall be subject to any penalty for failing to comply with a collection of information” if the Agency collecting the information failed to comply with certain statutory requirements.

³ The World Health Organization publishes and revises the ICD mortality codes. CDC NCHS *International Classification of Diseases, Tenth Revision (ICD-10)* (Feb. 13, 2020), (<https://www.cdc.gov/nchs/icd/icd10.htm>.) The ICD “is designed to promote international comparability in the collection, processing, classification, and presentation of mortality statistics.” (*Id.*)

However, even § 3512 “does not afford an independent cause of action; it merely serves as a defense to an enforcement action.” *Util. Air Regulatory Grp. v. EPA*, 744 F.3d 741, 750 n.6 (D.C. Cir. 2014) (“UARG”) (citing cases); *Saco River Cellular, Inc. v. FCC*, 133 F.3d 25, 32 (D.C.Cir.1998). Plaintiffs do not allege they are subjects of an enforcement action; rather, they contest the collection of COVID-19 data, “generally.” (ECF No. 27, PageID # 255.) Plaintiffs can find no legal support for their claims under the PRA because there is no right to judicial review.

Second, the IQA “does not create any legal right to information or its correctness.” *Leavitt*, 440 F.3d at 159; *Zero Zone, Inc.*, 832 F.3d at 683, n. 25 . Plaintiffs’ chief complaint is that Federal Defendants are presenting information about COVID-19 that is inaccurate and misleading. (ECF No. 27, PageID # 252-53, 259-60, 263-66.) Plaintiffs could have pursued an administrative request to have information corrected, but they do not allege that they even tried. *See HHS Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated to the Public* (Oct. 1, 2002), <https://aspe.hhs.gov/report/hhs-guidelines-ensuring-and-maximizing-quality-objectivity-utility-and-integrity-information-disseminated-public>. The IQA simply does not provide a private right of action for Plaintiffs to file their complaint in federal district court.

Based on the foregoing, there is no private right of action under the PRA and IQA, and this Court lacks jurisdiction. Therefore, Plaintiffs’ second Amended Complaint should be dismissed.

b. No Standing under the APA and Article III

“Where the party does not rely on any specific statute authorizing invocation of the judicial process, the question of standing depends upon whether the party has alleged such a ‘personal stake in the outcome of the controversy.’” *Sierra Club* , 405 U.S. at 732 (quoting *Baker v. Carr*, 369 U.S. 186, 204 (1962)). To establish standing, Plaintiffs must allege (1) he or she “suffered an ‘injury in fact’ that is ‘concrete and particularized’ and ‘actual or imminent, not conjectural or hypothetical’ ”; (2) the injury is “‘fairly traceable to the challenged action of the defendant’”; and (3) it is likely “‘that the injury will be redressed by a favorable decision.’” *Bennet*, 520 U.S. at

167, (quoting *Defenders of Wildlife*, 504 U.S. at 560-61.)

Also, Plaintiffs must demonstrate standing for each claim for relief. *See City of Los Angeles v. Lyons*, 461 U.S. 95, 106 (1983). They seek injunctive relief in the forms of a preliminary injunction and a writ of mandamus. (ECF No. 27, Page ID#265-66.) Therefore, the injury analysis is two-fold; Plaintiffs must show both past injury and a “real and immediate” threat of future injury. *Gaylor v. Hamilton Crossing CMBS*, 582 F. App’x 576, 579 (6th Cir. 2014) (citing *Lyons*, 461 U.S. at 102-03) (“The ‘threat’ of a prospective injury must be real and immediate and not premised upon the existence of past injuries alone.”) A writ of mandamus is an extraordinary remedy, thus Plaintiffs must show their right to issuance of the writ is “clear and indisputable.” *Will v. United States*, 389 U.S. 90, 95 (1967) (quoting *De Beers Consol. Mines, Ltd. v. United States*, 325 U.S. 212, 217 (1945); *see also Ohio A. Philip Randolph Inst. v. Larose*, 761 F. App’x 506, 512 (6th Cir. 2019) (quoting *Cheney v. U.S. Dist. Court for D.C.*, 542 U.S. 367, 381 (2004)). Plaintiffs fail to demonstrate standing and cannot meet the high standards for the relief they seek.

First, Plaintiffs do not allege a concrete, actual or imminent injury. (ECF No. 27, PageID # 248-67.) Alleged “injuries” consist of being “wrongly accused, ... censored, ... defamed, ... suffer[ing] economic loss, ... and ... violations of [the right] to freedom of movement, ... religion, free speech.” (*Id.*, PageID # 252.) Plaintiffs fail to identify concrete details or particularized facts showing an actual injury occurred. (*Id.*) For example, Plaintiff Ohio Stands Up! alleges that its “First Amendment rights to free speech and association have been violated” due to COVID-19 emergency mandates and “false data,” but these allegations alone do not demonstrate an injury. (*Id.*) To establish organizational standing, Ohio Stands Up! must show members of its organization have suffered injury in fact. *Sierra Club*, 405 U.S. at 734-35 (“the ‘injury in fact’ test requires more than an injury to a cognizable interest. It requires that the party seeking review be himself among the injured.”) Plaintiffs describe this organization’s sole purpose as “to challenge the state of emergency Ohio (“Emergency”), challenge the various emergency

mandates,” ... “uphold Constitutional rights, and educate about the realities of COVID-19.” (*Id.* PageID # 251.) Plaintiffs fail to show any of the members of Ohio Stands Up! have suffered “legal wrong,” *Lujan v. Nat’l Wildlife Fed’n*, 497 U.S. 871, 833 (1990), “palpable economic injuries,” or concrete harm. *Sierra Club*, 405 U.S. at 733 (rejecting organizational standing when club failed to show “a direct stake in the outcome.”) *Id.* at 740. Ohio Stands Up! lacks standing because they fail to show injury in fact and seek “to do no more than vindicate their own value preferences through the judicial process.” *Id.*

Turning to the individual Plaintiff Kristen Beckman (“Beckman”), she also lacks standing. The second Amended Complaint describes Beckman as a “private citizen,” and does not state she is a member of Ohio Stands Up! (ECF No. 27, PageID # 252.) She alleges a medical exemption and firmly held religious belief prevents her from wearing a mask, but none of these facts, even if true, establish an actual injury. (*Id.*) Beckman states a mandatory quarantine placed a burden on her “Constitutional right to travel,” but she does not allege concrete injury due to the mandatory quarantine or state how she was damaged. (*Id.*, PageID # 252-53.) Her family members’ “fear” and “ostracizing” are not an injuries in fact; they are more akin to “abstract injur[ies]” which are not enough to establish standing. (*Id.*); *Lyons*, 461 U.S. at 101-02. Dr. Douglas Frank is also listed in the “Parties” section of the second Amended Complaint, but he is not a party in the caption of the case, a violation of Fed. R. Civ. P. 10, nor is it alleged he is a member of Ohio Stands Up! (ECF No. 27, PageID # 253.) Even if viewed as a party, Dr. Frank has no standing because he only complains of “difficulties” in launching his business and “public ridicule.” These claims do not show concrete injury or meet the other elements required to establish standing. *Lyons*, 461 U.S. at 101-02.

Further, neither Beckman nor Ohio Stands Up! show a threat of future injury. The emergency mandates Plaintiffs complain of have been lifted, restrictions on gatherings are being eased, and as the public becomes vaccinated travel has also increased. *Mike DeWine Governor of Ohio COVID-19 Update: Quarantine Health Order, Mass Vaccination Clinic, Economic Update*

(April 27, 2021) <https://governor.ohio.gov/wps/portal/gov/governor/media/news-and-media/covid19-update-04272021>; *Lyons*, 461 U.S. at 102. “The equitable remedy is unavailable absent a showing of irreparable injury, a requirement that cannot be met where there is no showing of any real or immediate threat that the plaintiff will be wronged again-...” *Id.* at 111.

Furthermore, Plaintiffs’ alleged injuries do not even fall within the “zone of interests” of the PRA and IQA, the statutes whose alleged violations form the basis for Plaintiffs’ complaint. *Sierra Club*, 405 U.S. at 733; *see also Lexmark Int’l, Inc. v. Static Control Components, Inc.*, 572 U.S. 118, 127 (2014). Plaintiffs fail the “zone of interests test” because they cannot show that their interests in not wearing masks, not being “fact checked” about COVID-19 data, not being required to stay at home due to a pandemic, or not being subject to general embarrassment are within the zone of interests to be regulated by the PRA or IQA. *See Bennett*, 520 U.S. at 163 (quoting *Ass’n of Data Processing Serv. Orgs., Inc. v. Camp*, 397 U.S. 150, 153 (1970) (holding zone of interests test to be “whether the interest sought to be protected by the complainant is arguably within the zone of interests to be protected or regulated by the statute or constitutional guarantee in question.”) The zone of interests test reflects the fact that Congress does not intend to extend a cause of action to “plaintiffs who might technically be injured in an Article III sense but whose interests are unrelated to the statutory prohibitions ...” they seek to enforce. *Thompson v. N. Am. Stainless, LP*, 562 U.S. 170, 178 (2011). Here, Plaintiffs’ interests ““are so marginally related to or inconsistent with the purposes implicit in the statute that it cannot reasonably be assumed that Congress intended to permit the suit.”” *Match-E-Be-Nash-She-Wish Band of Pottawatomi Indians v. Patchak*, 567 U.S. 209, 225 (2012) (quoting *Clarke v. Sec. Ind. Ass’n*, 479 U.S. 388, 399 (1987)).

Second, Plaintiffs fail to show their “injuries” are traceable to Federal Defendants’ conduct. For example, Beckman claims her employer’s quarantine policy was the source of her injury, but she fails to trace this to Federal Defendants’ conduct. (ECF No. 27, PageID # 252.) To date, there have been no federal quarantines or stay at home mandates. Ohio Stands Up! claims it was

“censored on social media.” *Id.* Plaintiffs’ allegations focus on the actions of third parties such as the state of Ohio, private companies, and social media networks; not Federal Defendants’ actions. (*Id.*) *Bennett*, 520 U.S. at 169 (quoting *Defenders of Wildlife*, 504 U.S. at 560-61 (“as we have said, it does not suffice if the injury complained of is ‘th[e] result [of] the *independent* action of some third party not before the court,...”) Therefore, Plaintiffs fail to establish an injury traceable to Federal Defendants’ actions.

Third and finally, Plaintiffs’ alleged injuries would not be redressed by a decision in their favor. Even if the Court were to issue the injunctions Plaintiffs’ desire, they would have no binding effect on the behavior of the state of Ohio, social media platforms, or private companies. (*See* ECF No. 27, PageID # 265.) A decision in Plaintiffs’ favor cannot force Beckman’s employer to change its quarantine policy, force Beckman’s son’s hockey team to change its policies on mask wearing, force Beckman’s family to socialize with her, or prevent the users of social media platforms from “fact check[ing].” (*Id.* PageID # 252.) Also, a decision in Plaintiffs’ favor cannot force the public to agree with Ohio Stands Up! on issues regarding COVID-19. (*Id.*)

Therefore, based on the foregoing, Plaintiffs lack standing, and their claims should be dismissed.

B. Plaintiffs’ second Amended Complaint Fails to State a Claim

Plaintiffs characterize The Alert as an agency rule and state that a change in this rule forms the basis of their claims under the APA. (ECF No. 27, PageID # 256.) Federal Defendants do not concede that CDC changed an agency rule or that The Alert is even an agency rule at all; however, if taken as true, Plaintiffs fail to show The Alert is “agency action” or “final agency action” as required to state a claim under the APA and Fed. R. Civ. P. 12(b)(6). *See Jama v. Dep’t of Homeland Sec.*, 760 F.3d 490, 495 (6th Cir. 2014) (lack of finality analyzed under Rule 12(b)(6)); *Sierra Club v. Jackson*, 648 F.3d 848, 853-54 (D.C. Cir. 2011) (final agency action is not a jurisdictional issue and challenges based on final agency action should be analyzed under Rule 12(b)(6)).

1. Plaintiffs' Fail to Show "Agency Action"

Section 704 of the APA grants judicial review of "[a]gency action made reviewable by statute and final agency action for which there is no other adequate remedy in court..." 5 U.S.C. § 704. "The APA expressly does not permit judicial review in those instances where 'statutes preclude judicial review' or 'agency action is committed to agency discretion by law.'" *Jama*, 760 F.3d at 495 (quoting 5 U.S.C. § 701(a)). As discussed above, both the IQA and the PRA specifically exclude judicial review. *Heckler*, 470 U.S. at 830; *Leavitt*, 440 F.3d at 158; 44 U.S.C. § 3507(d)(6).

However, even if judicial review were granted, Plaintiffs' claims would fail because they do not identify any agency rules or agency action as defined by the APA. (ECF No. 27, PageID # 257.) Pursuant to the Supreme Court holding in *Norton v. S. Utah Wilderness Alliance*, only five categories of decisions or outcomes qualify as agency action under the APA. 5 U.S.C. § 551(13); *Norton v. S. Utah Wilderness Alliance*, 542 U.S. 55, 62 (2004). These categories:

[I]nvolve circumscribed, discrete agency actions, as their definitions make clear: "an agency statement of ... future effect designed to implement, interpret, or prescribe law or policy" (rule); "a final disposition ... in a matter other than rule making" (order); a "permit ... or other form of permission" (license); a "prohibition ... or ... taking [of] other compulsory or restrictive action" (sanction); or a "grant of money, assistance, license, authority," etc., or "recognition of a claim, right, immunity," etc., or "taking of other action on the application or petition of, and beneficial to, a person" (relief).

Norton, 542 U.S. at 62 (quoting 5 U.S.C. §§ 551(4), (6), (8), (10), (11)). None of these categories apply to the case at hand.

The Alert in question was issued by the Division of Vital Statistics, NCHS, to inform the recipients "that a newly-introduced ICD code has been implemented to accurately capture mortality data for Coronavirus Disease 2019 (COVID-19) on death certificates."⁴ The NCHS is

⁴ See Steven Schwartz, PhD, Director – Division of Vital Statistics, NCHS, *National Vital Statistics System, COVID-19 Alert No. 2* (March 24, 2020) <https://www.cdc.gov/nchs/data/nvss/coronavirus/Alert-2-New-ICD-code-introduced-for-COVID-19-deaths.pdf>.

part of the CDC.⁵ Its purpose is to “conduct and support statistical and epidemiological activities for the purpose of improving the effectiveness, efficiency, and quality of health services in the United States.” 42 U.S.C. § 242k(a). Relevant to this case, Congress authorized the Secretary of HHS, through NCHS, to provide technical assistance to State and local jurisdictions; to prepare and distribute forms for mortality, morbidity, and other health data collection and compilation; and to collect mortality data. *See* 42 U.S.C. §§ 242k(d), (g), and (h). The statute does not authorize NCHS to accomplish this through rulemaking. *Id.*

The NCHS issued The Alert as technical assistance to “state statistical staff” responsible for preparing mortality data. *See* Steven Schwartz, PhD, Director – Division of Vital Statistics, NCHS, *National Vital Statistics System, COVID-19 Alert No. 2* (March 24, 2020) <https://www.cdc.gov/nchs/data/nvss/coronavirus/Alert-2-New-ICD-code-introduced-for-COVID-19-deaths.pdf>. Providing this type of technical assistance is part of the mission of the NCHS. *See* 42 U.S.C. §§ 242k(d), (g), and (h). The Alert did not implement, interpret, or prescribe law or policy and therefore was not an agency rule and does not qualify as agency action. *Norton*, 542 U.S. at 62 (quoting 5 U.S.C. §§ 551(4), (6), (8), (10), (11)).

Further, the 2003 Handbooks Plaintiffs reference are not federal agency rules or action. In 2003, the HHS, CDC, and NCHS published the *Physicians’ Handbook on Medical Certification of Death*⁶ (“*Physicians’ Handbook*”) and the *Medical Examiners’ and Coroners’ Handbook on Death Registration and Fetal Death Reporting*⁷ (“*Coroners’ Handbook*”)(hereafter collectively “2003 Handbooks”). The 2003 Handbooks serve as an adaptable “model” and acknowledge that “registration of deaths is a State function supported by individual State laws and regulations.” *See*

⁵ CDC NCHS Organization (Apr. 20, 2021), <https://www.cdc.gov/nchs/about/organization.htm>.

⁶ The CDC, *Physicians’ Handbook on Medical Certification of Death* (2003), https://www.cdc.gov/nchs/data/misc/hb_cod.pdf.

⁷ The CDC *Medical Examiners’ and Coroners’ Handbook on Death Registration and Fetal Death Reporting* (2003) https://www.cdc.gov/nchs/data/misc/hb_me.pdf.

Physicians' Handbook, "Introduction," "U.S. Standard Certificate of Death," at 3. The 2003 Handbooks contain almost identical guidance for completing death certificates, and state that "[t]he cause-of-death section, ... , follows guidelines recommended by the World Health Organization." See *Physicians' Handbook*, "Doubt and cause of death," at 9; see also *Coroners' Handbook*, "Medical Certification of Death," "Cause of Death." As with The Alert, the 2003 Handbooks do not qualify as "agency rules" or "agency action," but rather technical assistance provided pursuant to the mission of the NCHS. *Norton*, 542 U.S. at 62 (quoting 5 U.S.C. §§ 551(4), (6), (8), (10), (11)).

Therefore, based on the foregoing, Plaintiffs fail to state a claim under the APA because there is no agency action that implements, interprets, or prescribes law or policy.

2. Plaintiffs Fail to Show "Final" Agency Action as Required by the APA

Even if the Court were to find The Alert qualifies as "agency action," Plaintiffs fail to allege their injuries stem from a "final agency action for which there is no other adequate remedy in court." *Jama*, 760 F.3d at 495 (quoting *Bangura v. Hansen*, 434 F.3d 487, 500 (6th Cir. 2006)); (ECF No. 27, PageID # 256.) The Sixth Circuit analyzes the question of whether agency action is final, utilizing the two-prong test set out by the Supreme Court in *Bennett*. First, the action must "mark the 'consummation' of the agency's decisionmaking process" and, thus, cannot be "merely tentative or interlocutory." *Bennett*, 520 U.S. at 177-78. Second, the action must be one by which "rights or obligations have been determined," or from which "legal consequences will flow." *Id.* at 178 (quoting *Port of Boston Marine Terminal Ass'n*, 400 U.S. at 71); see *Franklin v. Massachusetts*, 505 U.S. 788, 797 (1992) ("The core question is whether the agency has completed its decisionmaking process, and whether the result of that process is one that will directly affect the parties.")

The first *Bennett* prong "look[s] at finality from the agency's perspective (whether the action represents the culmination of the agency's decisionmaking)..." *Soundboard Ass'n v. FTC*, 888 F.3d 1261, 1271 (D.C. Cir. 2018). Decisions that are "tentative" or issued by a "subordinate

official” are not considered final. *Franklin*, 505 U.S. at 796 (quoting *Abbott Labs. v. Gardner*, 387 U.S. 136, 151 (1967)); see, e.g., *Id.* at 798 (agency reports that serve as a tentative recommendation are not considered final, binding determinations). Here, The Alert cannot be considered the “culmination of the agency’s decisionmaking,” because similar alerts were issued throughout the course of the pandemic as clinical data was gathered.⁸ These alerts were not created as part of a formal review or rule-making process, rather, they were provided as technical assistance throughout the pandemic to local and state authorities.

The second *Bennett* prong examines finality from the regulated parties’ perspective, questioning whether the alleged agency action determines the rights and obligations of a party or causes them to suffer legal consequences. *Berry v. U.S. Dep’t of Labor*, 832 F.3d 627, 633 (6th Cir. 2016). “In other words, it must have a ‘sufficiently direct and immediate’ impact on the aggrieved party and a ‘direct effect on [its] day-to-day business.’” *Id.*; see also, *FTC v. Standard Oil Co. of Cal.*, 449 U.S. 232, 239-41 (1980); *Indus. Customers of Nw. Utils. v. Bonneville Power Admin.*, 408 F.3d 638, 646 (9th Cir. 2005); *Reliable Automatic Sprinkler Co. v. Consumer Prod. Safety Comm’n*, 324 F.3d 726, 731 (D.C. Cir. 2003). Here, Plaintiffs fail to state how The Alert has directly and immediately impacted their day-to-day business. The Alert imposes no legal obligations on Plaintiffs and no requirement that Plaintiffs comply with its terms; Plaintiffs do not allege The Alert applies to them in any way. (ECF No. 27, PageID # 257.) The Alert is not a determination of Plaintiffs’ rights or obligations; therefore it is not agency action. See *Flue-Cured*

⁸ Alert 1, see Steven Schwartz, PhD, Director – Division of Vital Statistics, NCHS, *National Vital Statistics System, Guidance for Certifying COVID-19 Deaths* (March 4, 2020), guidance on certifying COVID-19 deaths, <https://www.cdc.gov/nchs/data/nvss/coronavirus/Alert-1-Guidance-for-Certifying-COVID-19-Deaths.pdf>; Alert 2, see Steven Schwartz, PhD, Director – Division of Vital Statistics, NCHS, *National Vital Statistics System, COVID-19 Alert No. 2* (March 24, 2020), <https://www.cdc.gov/nchs/data/nvss/coronavirus/Alert-2-New-ICD-code-introduced-for-COVID-19-deaths.pdf>; see also CDC NCHS NVSS Vital Statistics Reporting Guidance Report No. 3 (April 2020), *Guidance for Certifying Deaths Due to Coronavirus Disease 2019 (COVID-19)* <https://www.cdc.gov/nchs/data/nvss/vsrg/vsrg03-508.pdf>.

Tobacco Coop. Stabilization Corp. v. U.S. EPA, 313 F.3d 852, 859–62 (4th Cir. 2002) (any agency action is not reviewable under the APA where it produces only “coercive pressures on third parties” but ultimately creates no legal rights, obligations, or consequences.)

Based on the foregoing, Plaintiffs’ fail to allege a final agency action subject to judicial review and their second Amended Complaint should be dismissed.

3. Plaintiffs’ Fail to State a Claim for Relief under *Iqbal*

The Court in *Iqbal* referred to a two-pronged approach in determining the sufficiency of a pleading when challenged by a motion to dismiss for failure to state a claim under Fed. R. Civ. P. 12(b)(6). First, the Court held that “the tenet that a court must accept as true all of the allegations contained in a complaint is inapplicable to legal conclusions.” *Iqbal*, 556 U.S. at 678. Second, “only a complaint that states a plausible claim for relief survives a motion to dismiss.” *Id.* at 679. This means the complaint must contain “factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged.” *Id.* at 678.

In the instant case, the entirety of Plaintiff’s complaint consists of unsupported legal conclusions. The second Amended Complaint is no more than an “unadorned, the-defendant-unlawfully-harmed-me accusation.” *Id.* at 678. Specific claims are hard to identify. For example, Plaintiffs assert generally that “[t]he reporting of data that is known to be misleading . . . [which] is used to set policy . . . [has] profound implications for private citizens and businesses, including innumerable, unprecedented, prolonged invasions of their Constitutional rights.” (ECF No. 27, PageID # 263-64.) Without facts supporting the conclusion that the data is misleading or alleging concrete damages to citizens and businesses, there is no valid complaint. Conclusions such as rules creating “chaos throughout the nation, cost[ing] untold trillions of dollars, and . . . justify[ing] Emergency Mandates that have harmed the Plaintiffs” do not state a claim for relief and the Court is not required to accept these conclusions as true. (*Id.* PageID # 262.); *see also Iqbal*, 556 U.S. at 678.

Focusing on the second prong of *Iqbal*, Plaintiffs’ second Amended Complaint does not

state a plausible claim for relief. *Iqbal*, 556 U.S. at 679. Such a determination is “a context-specific task that requires the reviewing court to draw on its judicial experience and common sense.” *Id.* It is not plausible or even logical to believe that Federal Defendants and their individual directors conspired to mislead the public during the COVID-19 pandemic. It defies common sense to think that Federal Defendants created agency rules that would exaggerate the COVID-19 death toll to scare the public, violate their constitutional rights, harass citizens, and close businesses. Nor is it reasonable to believe that an alleged change in death reporting guidance allows physicians to falsely inflate the number of COVID-19 deaths in order to be eligible for additional funding. (ECF No. 27, PageID # 261.)

Plaintiffs’ second Amended Complaint is devoid of factual content that allows this Court to draw a reasonable inference that Federal Defendants are liable. Therefore, Plaintiffs’ second Amended Complaint should be dismissed for failure to state a claim.

V. CONCLUSION

For the reasons set forth herein, Plaintiffs have failed to establish jurisdiction and failed to state a claim. Therefore, Federal Defendants respectfully request this Honorable Court dismiss Plaintiffs’ second Amended Complaint with prejudice, pursuant to Fed. R. Civ. P. 12 (b)(1) and (6).

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE WITH LOCAL RULE 7.1(f)

Pursuant to Local Rule 7.1(f), undersigned counsel certifies that the foregoing Memorandum in Support is Twenty (20) pages in length and within the page limitation of a matter assigned to the standard track or unassigned.

s/ Angelita Cruz Bridges
Angelita Cruz Bridges
Assistant U.S. Attorney